IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LIABILITY LITIGATION This Document Relates to: Second Amended Master Long Form Complaint For Personal Injuries And Damages, And Demand For Jury Trial (ECF No. 2505)	Master Docket: No. 21-mc-1230-JFC MDL No. 3014 (Oral Argument Requested)

REPLY MEMORANDUM IN FURTHER SUPPORT OF PHILIPS RS NORTH AMERICA LLC'S MOTION TO DISMISS

John P. Lavelle, Jr. (PA54279)
john.lavelle@morganlewis.com
Lisa C. Dykstra (PA67271)
lisa.dykstra@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
2222 Market Street
Philadelphia, PA 19103-3007
Tel: 215.963.5000

Wendy West Feinstein (PA86698)
wendy.feinstein@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
One Oxford Center, 32nd Floor
Pittsburgh, PA 15219-6401
Tel: 412.560.3300

Counsel for Defendant Philips RS North America LLC

TABLE OF CONTENTS

Page

ARGUMENT 1

I. PLAINTIFFS' NEGLIGENT RECALL/FAILURE TO RECALL CLAIMS FAIL. 1

A. The Negligent Execution of/Failure to Recall Claims Are Preempted 1

B. The Primary Jurisdiction Doctrine Bars Plaintiffs' Negligent Execution of the Recall Claim. 2

C. Negligent Failure to Recall is Not a Cause of Action in Two States. 4

II. NEGLIGENCE *PER SE* IS NOT A CAUSE OF ACTION IN FOUR STATES. 4

III. STATE PRODUCT LIABILITY ACTS SUBSUME CERTAIN CLAIMS. 4

IV. PLAINTIFFS IMPROPERLY ASSERT THEORIES OF LIABILITY UNAVAILABLE UNDER FOUR STATES' PRODUCT LIABILITY STATUTES. 5

V. PLAINTIFFS' FRAUD CLAIM MUST BE DISMISSED UNDER THE LAWS OF THIRTEEN STATES FOR FAILURE TO PLEAD A SPECIAL RELATIONSHIP. 6

VI. PLAINTIFFS' CONSUMER PROTECTION CLAIMS FAIL. 7

A. 16 Consumer Protection Statutes Do Not Cover Prescription Medical Devices. 7

B. Omissions Cannot Support Wisconsin Deceptive Trade Practices Act Claims. 9

C. Seven Consumer Protection Claims Fail for Lack of Prerequisites to Suit. 9

D. Certain Plaintiffs Lack Statutory Standing to Sue. 10

CONCLUSION 10

TABLE OF AUTHORITIES

Page(s)

CASES

Bell v. Boehringer Ingelheim Pharms., Inc.,
No. CV 17-1153, 2018 WL 2447788 (W.D. Pa. May 31, 2018) 1

Brass Metal Prod., Inc. v. E-J Enters., Inc.,
984 A.2d 361 (Md. Ct. Spec. App. 2009) 6

Buckman Co. v. Plaintiffs' Legal Comm.,
531 U.S. 341 (2001) 1

Bush v. Thoratec Corp.,
837 F. Supp. 2d 603 (E.D. La. 2011) 2

Castrol, Inc. v. Pennzoil Co.,
987 F.2d 939 (3d Cir. 1993) 6

Cohen v. Subaru of America, Inc.,
2022 WL 721307 (D.N.J. Mar. 10, 2022) 2, 4

Collins v. Davol, Inc.,
56 F. Supp. 3d 1222 (N.D. Ala. 2014) 7, 9

Costa v. FCA US LLC,
542 F. Supp. 3d 83 (D. Mass. 2021) 6

Elward v. Electrolux Home Prods., Inc.,
264 F. Supp. 3d 877 (N.D. Ill. 2017) 5

Fusco v. Uber Tech., Inc.,
Civ. A. No. 17-00036, 2018 WL 3618232 (E.D. Pa. Jul. 27, 2018) 6

Golden, M.D. v. Brown, M.D.,
No. 17CV30568, 2017 WL 4239015 (Colo. Dist. Ct. Sep. 24, 2017) 7

Hart v. City of Phila.,
779 F. App'x 121 (3d Cir. 2019) 5

Hazzouri v. W. Pittston Borough,
416 F. Supp. 3d 405 (M.D. Pa. 2019) 10

In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.,
537 F. Supp. 3d 679 (D.N.J. 2021) 10

TABLE OF AUTHORITIES
(continued)

Page(s)

In re Bextra & Celebrex Mktg. Sales Pracs.,
495 F. Supp. 2d 1027 (N.D. Cal. 2007) 8

In re Trader Joe's Co. Dark Chocolate Litig.,
No. 3:23-CV-0061-RBM-KSC, 2024 WL 1319725 (S.D. Cal. Mar. 27, 2024) 3

In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.,
2020 WL 7418006 (D.N.J. Dec. 18, 2020) 3, 4

In re Vioxx Class Cases,
103 Cal. Rptr. 3d 83 (Cal. Ct. App. 2009) 8

Johnson v. Draeger Safety Diag., Inc.,
594 F. App'x 760 (3d Cir. 2014) 6

Jordan v. Flynt,
240 S.E.2d 858 (Ga. 1977) 6

Kurer v. Parke, Davis & Co.,
679 N.W.2d 867 (Wis. Ct. App. 2004) 4

National Women's Health Network, Inc. v. A. H. Robins Co.,
545 F. Supp. 1177 (D. Mass. 1982) 1, 2

Nelson v. C.R. Bard, Inc.,
553 F. Supp. 3d 343 (S.D. Miss. 2021) 5

NetQuote, Inc. v. Byrd,
504 F. Supp. 2d 1126 (D. Colo. 2007) 10

Orson, Inc. v. Miramax Film Corp.,
79 F.3d 1358 (3d Cir. 1996) 9

Otis-Wisher v. Medtronic, Inc.,
616 F. App'x 433 (2d Cir. June 9, 2015) 7, 8, 9

Palm v. Taurus Int'l Mfg., Inc.,
No. 22-CV-337, 2022 WL 17714600 (N.D. Ind. Dec. 15, 2022) 5

Pease v. Abbott Lab'ys, Inc.,
No. CIV. 12-1844, 2013 WL 174478 (D. Md. Jan. 16, 2013) 7, 9

Penn-Mont Benefit Servs., Inc. v. Crosswhite,
No. CIV.A. 02-1980, 2003 WL 203570 (E.D. Pa. Jan. 29, 2003) 4

Phelps v. Wyeth, Inc.,
938 F. Supp. 2d 1055 (D. Or. 2013) 4

TABLE OF AUTHORITIES
(continued)

Page(s)

Plubell v. Merck & Co., Inc.,
289 S.W.3d 707 (Mo. Ct. App. 2009).....8

Polk v. KV Pharm. Co.,
No. 09-CV-00588, 2011 WL 6257466 (E.D. Mo. Dec. 15, 2011).....8

Price v. Blood Bank of Del., Inc.,
790 A.2d 1203 (Del. 2002).....4

Reeves v. PharmaJet, Inc.,
846 F. Supp. 2d 791 (N.D. Ohio 2012).....7

Riegel v. Medtronic, Inc.,
552 U.S. 312 (2008).....2

Seaman v. Colvin,
145 F. Supp. 3d 421 (E.D. Pa. 2015).....9

Statford v. SmithKline Beecham Corp.,
No. 2:07–CV–639, 2008 WL 2491965 (S.D. Ohio Jun. 17, 2008).....5

Sun Chem. Corp. v. Fike Corp.,
235 A.3d 145 (N.J. 2020).....5

Tietsworth v. Harley-Davidson, Inc.,
677 N.W.2d 233 (Wis. 2004).....9

West Virginia ex rel. McGraw v. Bristol Myers Squibb Co.,
No. 13-1603, 2014 WL 93569 (D.N.J. Feb. 26, 2014).....8

White v. Beech-Nut Nutrition Co.,
No. 23-220-cv, 2024 WL 194699 (2d Cir. Jan. 18, 2024).....3, 7, 8, 9

White v. Wyeth,
705 S.E.2d 828 (W. Va. 2010).....7

STATUTES

21 U.S.C. § 360.....2

21 U.S.C. § 360h(d).....2, 3

Wisconsin Deceptive Trade Practices Act.....9

RULES

Fed. R. Civ. P. 12(b)(6).....1, 6

Philips RS North America LLC ("Respironics") moved to dismiss (ECF No. 2574) ("MTD") certain claims asserted in Plaintiffs' second amended personal injury complaint (ECF No. 2505) (the "PISAC"). Plaintiffs' Opposition (ECF No. 2714) ("Opp.") concedes that several of those claims are subject to dismissal and fails to salvage the remaining claims.

ARGUMENT

I. PLAINTIFFS' NEGLIGENT RECALL/FAILURE TO RECALL CLAIMS FAIL.

A. The Negligent Execution of/Failure to Recall Claims Are Preempted.

Plaintiffs assert three arguments to avoid preemption of their recall-related claims. None have merit. ***First***, they cite express preemption cases to argue that preemption may not be resolved on the pleadings. Opp. at 2. But Respironics' arguments are grounded in implied, not express, preemption. This Court and others have held that implied preemption is a basis for dismissal under Rule 12(b)(6) where, as here, the grounds for preemption are alleged in the complaint. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48 (2001); *Bell v. Boehringer Ingelheim Pharms., Inc.*, No. CV 17-1153, 2018 WL 2447788 at *6 (W.D. Pa. May 31, 2018) (Conti, J.).

Second, on negligent failure to recall, Plaintiffs disregard *National Women's Health Network, Inc. v. A. H. Robins Co.* on the grounds that plaintiffs there sought remedial injunctive relief, not monetary damages like here. 545 F. Supp. 1177 (D. Mass. 1982). But *Robins* specifically noted that the FDCA "does not afford a right of action for damages." *Id*. at 1179. Further, in analyzing the legislative history, the court in *Robins* set out that:

> [T]he Secretary [of the FDA] should have considerable discretion in determining whether or not users of devices must be notified of defects in any given case" and that such discretion "would be eliminated by the private right of action" and "the major advantages of enforcement through the Secretary would be lost, including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a unitary enforcement policy.

Id. at 1179-80. As such, "state law [claims] which would put these same powers in other hands

must be deemed foreclosed." *Id*. at 1181. In other words, Plaintiffs' claim would obstruct the FDA's discretion as to when to seek a recall and impose additional conditions not contemplated by the federal regime.[1]

Third, on the negligent recall claim, Plaintiffs notably omit analysis of "obstacle" preemption, which was the basis for the holding in *Cohen v. Subaru of America, Inc.* that "applying negligence law of more than twenty states . . . would undermine the [federal regulations]'s comprehensive statutory scheme for commencing and carrying out recalls." 2022 WL 721307, at *40 (D.N.J. Mar. 10, 2022). *Cohen* thus reflects that the imposition of unspecified state law duties stands as an obstacle to the FDA's regulatory framework for assessing and overseeing the recall process. *Id*. Plaintiffs invoke 21 U.S.C. § 360h(d)'s savings clause, but section 360h(d) is not implicated here because the recall was undertaken voluntarily, not pursuant to any order. *See Bush v. Thoratec Corp.*, 837 F. Supp. 2d 603, 607 (E.D. La. 2011) (section 360h(d) controls only when "[c]ompliance with an order issued ***under this section*** [is implicated]" (emphasis in original)).[2]

B. Primary Jurisdiction Bars Plaintiffs' Negligent Execution of the Recall Claim.

The FDA has exclusive authority over the execution of the recall, implicating the primary jurisdiction doctrine and barring Plaintiffs' negligent execution of the recall claim. *See* MTD at 3-6. To evade this outcome, Plaintiffs mischaracterize their claim and disregard the FDA's active and continuing oversight of the recall. *See* Opp. at 5-8. Plaintiffs' arguments lack merit.

---

[1] Contrary to their assertion, Opp. at 3 n.7, Plaintiffs' claims do not fit into the "narrow gap" for avoiding preemption that was articulated in Respironics' prior briefing. Without identifying specific duty that gives rise to Plaintiffs' recall-related claims, their broad-stroke allegations do not demonstrate that their claims are based on state law duties, rather than violations of the FDCA.

[2] The subsequent notification order under section 518(a) of the FDCA is not relevant to Plaintiffs' section 360h(d) argument. The existence of the section 518(a) notification order, however, reinforces the propriety of dismissal on primary jurisdiction grounds, *infra* at Section I.B. Further, section 360h(d) "'could not possibly mean that all state-law claims are not pre-empted . . . .'" *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 n.4 (2008).

Contrary to Plaintiffs' assertions, Plaintiffs request ***both*** monetary and equitable damages under their negligent recall claim. *See* PISAC ¶ 442. Thus, as plainly alleged, this is not a claim for which "Plaintiffs seek only money damages." Opp. at 6. Next, Plaintiffs urge the court to bypass the four *Baykeeper* factors because "the delay occasioned by abstention would be costly and inefficient." *Id.* In support of this argument, Plaintiffs rely exclusively on out-of-circuit cases that, in any event, are readily distinguishable.[3] Unlike in those cases, here, the FDA's active oversight of the voluntary recall is both material and ongoing.[4]

As to the first and second *Baykeeper* factors, Plaintiffs urge the Court not to defer to the FDA because their negligent execution of the recall claim "does not require specific expertise." Opp. at 7. But the regulations cited in the MTD squarely contradict that assertion and, indeed, the Consent Decree reflects the FDA's continuing active oversight of Respironics' recall efforts—aspects of which are committed to the FDA's "sole discretion" and cannot proceed without the FDA's written approval. *See, e.g.*, Consent Decree at 9, 12, 14, 23. Plaintiffs' reliance on *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, 2020 WL 7418006 (D.N.J. Dec. 18, 2020), is misplaced as the court there did not consider any recall claims as part of its primary jurisdiction analysis.[5] As to the third and fourth factors, Plaintiffs claim "[t]here is no risk of inconsistent rulings," Opp. at 7, but this is wrong given the Consent Decree outlines specific procedures that Respironics must follow in carrying out the recall plan. And though Plaintiffs seek to temper their

---

[3] *See White v. Beech-Nut Nutrition Co.*, No. 23-220-cv, 2024 WL 194699, at *2 (2d Cir. Jan. 18, 2024) (declining to apply primary jurisdiction where the FDA "abandoned" its plans to finalize action levels for the chemicals at issue); *In re Trader Joe's Co. Dark Chocolate Litig.*, No. 3:23-CV-0061-RBM-KSC, 2024 WL 1319725, at *15 (S.D. Cal. Mar. 27, 2024) (pointing to the uncertainty of FDA action as a reason for declining to abstain based on primary jurisdiction).

[4] Respironics recently agreed to a consent decree with the DOJ and FDA that outlines the FDA's continued involvement in the recall. *See United States v. Philips RS N. Am. LLC*, No. 2:24-cv-00505-RJC (W.D. Pa.) (Colville, J.) (ECF No. 4-1) ("Consent Decree").

[5] Plaintiffs' reliance on section 360h(d) is also misplaced as discussed above. *Supra* p.2.

concession that the fourth factor favors abstention by citing to *Cohen*, their reliance on that case is unavailing. *Cohen* states that initiation of a recall "***alone*** is insufficient to justify abstention," 2022 WL 721307, at *37 (emphasis added), but ***all*** factors weigh in favor of abstention here.

C. Negligent Failure to Recall Is Not a Cause of Action in Two States.

There is no extra-statutory duty to recall under Illinois and Oklahoma law. *See* MTD at 6 n.4. Plaintiffs incorrectly rely on cases that consider recall allegations in the context of a ***general negligence claim***, not a negligent failure to recall claim. *See* Opp. at 8.

II. NEGLIGENCE *PER SE* IS NOT A CAUSE OF ACTION IN FOUR STATES.

Delaware, Oregon, Rhode Island, and Wisconsin do not recognize negligence *per se* as an independent claim. MTD at 6 n.5. Plaintiffs concede the point under Rhode Island law. Opp. at 8 n.12. Plaintiffs also concede that in Delaware, Oregon, and Wisconsin, negligence *per se* is subsumed within a cause of action for negligence, *id.* at 8 n.13, and Plaintiffs' cases affirm that point.[6] Plaintiffs' purported negligence *per se* claims under the laws of these states fail.[7]

III. STATE PRODUCT LIABILITY ACTS SUBSUME CERTAIN CLAIMS.

Plaintiffs continue to argue unsuccessfully that certain common law claims are not subsumed by state product liability acts. ***First***, in support of their Indiana breach of warranty claims Plaintiffs rely solely on *Valsartan* and fail to contend with subsequent caselaw distinguishing between breach of warranty claims (referenced in *Valsartan*) seeking economic damages, which are not subsumed, and breach of warranty claims like those here seeking only

---

[6] *See Price v. Blood Bank of Del., Inc.*, 790 A.2d 1203, 1213 (Del. 2002) (negligence *per se* "standing alone, does not establish liability"); *Phelps v. Wyeth, Inc.*, 938 F. Supp. 2d 1055, 1076 (D. Or. 2013) (negligence *per se* is one element "under a common-law theory of negligence"); *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 874-75 (Wis. Ct. App. 2004) ("A safety statute merely establishes a minimum standard of care[.]") (citation omitted).

[7] Respironics did not waive its challenge to Plaintiffs' claim for negligence *per se* under Delaware law. *See, e.g., Penn-Mont Benefit Servs., Inc. v. Crosswhite*, No. CIV.A. 02-1980, 2003 WL 203570, at *6 (E.D. Pa. Jan. 29, 2003).

personal injury damages, which are subsumed. *See Palm v. Taurus Int'l Mfg., Inc.*, No. 22-CV-337, 2022 WL 17714600, at *4-5 (N.D. Ind. Dec. 15, 2022). ***Second***, Plaintiffs assert that their fraud claims are not subsumed by the OPLA, but the OPLA governs common law fraud claims alleging a failure to warn like Plaintiffs' "fraud by omission" claims here. *See Statford v. SmithKline Beecham Corp.*, No. 2:07–CV–639, 2008 WL 2491965, at *8 (S.D. Ohio Jun. 17, 2008). ***Third***, the limited circumstances cited by Plaintiffs where Indiana, Mississippi, and New Jersey consumer protection claims have not been subsumed by those PLAs do not apply here. *See, e.g.*, *Sun Chem. Corp. v. Fike Corp.*, 235 A.3d 145, 155 (N.J. 2020) (holding that NJPLA and consumer protection claims may only co-exist when they "alleg[e] different theories of liability and seek[] dissimilar damages.").[8] Plaintiffs try to recover under the PLAs for alleged failure to warn, negligent failure to warn, common law fraud by omission, and negligent misrepresentation. *See, e.g.*, PISAC ¶¶ 1802-03. Those theories and requested damages squarely overlap with Plaintiffs' claims under various state consumer protection acts.[9]

IV. PLAINTIFFS IMPROPERLY ASSERT THEORIES OF LIABILITY UNAVAILABLE UNDER FOUR STATES' PRODUCT LIABILITY STATUTES.

Plaintiffs' claims under four states' PLAs improperly seek to recover on theories of liability not available under those statutes including medical monitoring under all four PLAs, and negligent failure to recall and negligent recall under the Louisiana, New Jersey, and Ohio PLAs. MTD at 8. Additionally, Plaintiffs' theories of liability premised on fraud, implied warranty, and consumer protection claims under Louisiana law and fraud claims under Ohio and New Jersey law cannot be

[8] *See also Nelson v. C.R. Bard, Inc.*, 553 F. Supp. 3d 343, 349 (S.D. Miss. 2021); *Elward v. Electrolux Home Prods., Inc.*, 264 F. Supp. 3d 877, 892 (N.D. Ill. 2017).

[9] Contrary to Plaintiffs' argument, Respironics did not waive its argument with respect to the Indiana PLA claim, and in any event the Third Circuit has routinely upheld district courts' decisions permitting new arguments to be raised on successive motions to dismiss. *See, e.g.*, *Hart v. City of Phila.*, 779 F. App'x 121, 125 (3d Cir. 2019).

asserted as theories of liability under those states' PLAs.[10]

V. PLAINTIFFS' FRAUD CLAIM MUST BE DISMISSED UNDER THE LAWS OF THIRTEEN STATES FOR FAILURE TO PLEAD A SPECIAL RELATIONSHIP.

Plaintiffs acknowledge their failure to plead a confidential or fiduciary relationship with Respironics under 13 states' laws that require such a relationship, and Plaintiffs' arguments that they satisfy exceptions to this pleading requirement fail. ***First***, Plaintiffs' contention that Georgia and Maryland recognize a purported "partial disclosure" exception is not supported by Plaintiffs' case law. *See* Opp. at 10.[11] For the remaining states, the cases Plaintiffs cite are inapposite because they involve a ***direct*** interaction and/or relationship between plaintiff and defendant rather than a remote manufacturer and a consumer as here. *Id.*

Second, even assuming *arguendo* that such exception existed in any of the 13 states, the exception does not apply because Plaintiffs have not pled any "partial disclosure" concerning the safety of the foam much less other required elements. Opp. at 10.[12] The marketing and other materials quoted in the PISAC do not include any "partial disclosure" about the safety of the foam; rather, they are all of a type deemed mere puffery by courts.[13] *Id.* (citing PISAC ¶¶ 86, 235-36,

---

[10] Even if Rule 12(b)(6) does not typically allow for the dismissal of only part of a claim, the unique procedural posture of this case requires otherwise. Allowing Plaintiffs to retain impermissible PLA theories of liability in the PISAC will only result in individual plaintiffs bringing deficient PLA claims in the future.

[11] *Jordan v. Flynt*, 240 S.E.2d 858, 863 (Ga. 1977) did not consider a duty to speak in the context of omission-based fraud. *Brass Metal Prod., Inc. v. E-J Enters., Inc.*, 984 A.2d 361 (Md. Ct. Spec. App. 2009) did not consider whether a duty to disclose may exist absent a fiduciary/confidential relationship, or whether partial disclosure could give rise to such a relationship.

[12] *See, e.g.*, *Costa v. FCA US LLC*, 542 F. Supp. 3d 83, 100–02 (D. Mass. 2021) (partial disclosure exception unavailable where plaintiff "ha[d] not identified a partial or ambiguous statement"). Plaintiffs also assert that all states recognize another two exceptions but do not discuss those exceptions. *See* Opp. at 10. If Plaintiffs, by referencing to their prior briefing, are attempting to argue that certain states recognize additional exceptions, those exceptions do not apply here. *See* Respironics' Citation Table C(1) (ECF 1827).

[13] *See, e.g.*, *Castrol, Inc. v. Pennzoil Co.*, 987 F.2d 939, 945 (3d Cir. 1993); *Fusco v. Uber Tech., Inc.*, Civ. A. No. 17-00036, 2018 WL 3618232, at *6–7 (E.D. Pa. Jul. 27, 2018) (collecting cases); *accord Johnson v. Draeger Safety Diag., Inc.*, 594 F. App'x 760, 766–67 (3d Cir. 2014).

549-54, 564). Nor can Plaintiffs rely on Respironics' purported statements from 2020 regarding whether the use of SoClean products would void available warranties. These alleged statements did not address the safety of PE-PUR foam, and the PISAC lacks allegations concerning Plaintiffs' use of SoClean products in reliance on these alleged statements. *Id.* (citing PISAC ¶¶ 237–42).

VI. PLAINTIFFS' CONSUMER PROTECTION CLAIMS FAIL.

A. 16 Consumer Protection Statutes Do Not Cover Prescription Medical Devices.

In *White v. Wyeth*, the West Virginia Supreme Court held: "Prescription drug cases are not the type of private causes of action contemplated under the terms and purposes of the WVCCPA ***because the consumer can not and does not decide what product to purchase***." 705 S.E.2d 828, 838 (W. Va. 2010) (emphasis added). The same applies to prescription medical devices. *See, e.g.*, *Golden, M.D. v. Brown, M.D.*, No. 17CV30568, 2017 WL 4239015, at *3 (Colo. Dist. Ct. Sep. 24, 2017) (holding Colorado Consumer Protection Act "does not apply to medical device claims.").

The 16 statutes at issue apply only to goods for ***"personal, family, or household use,"*** which FDA-regulated, physician-prescribed medical devices are not. *See* MTD at 10–13.[14] Plaintiffs attempt to manufacture a distinction between implantable devices and medical devices that a patient obtains pursuant to the doctor's prescription. Opp. at 12 & n.20. But this distinction has no basis in the statutes' context, wording, or purpose, and notably, Plaintiffs cannot cite ***a single*** case supporting it. Instead, Plaintiffs rely on a handful of outlier decisions, which, in addition to being wrongly decided per *White*, do not even concern medical devices, let alone

[14] *See, e.g.*, *Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433, 435 (2d Cir. June 9, 2015) (medical device "not available for consumer purchase"); *Collins v. Davol, Inc.*, 56 F. Supp. 3d 1222, 1232 (N.D. Ala. 2014) (medical devices are not "goods that are used or bought for use primarily for personal, family, or household purposes"); *Pease v. Abbott Lab'ys, Inc.*, No. CIV. 12-1844, 2013 WL 174478, at *2 (D. Md. Jan. 16, 2013) (prescription drug "selected by [plaintiff's] physician[,]. . . not as a consumer good, but as part of her course of medical treatment"); *see also Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 799 (N.D. Ohio 2012) ("prescription medical device "is not a good for personal, family or household use[.]").

address whether such devices are "personal, household, or family goods." Opp. at 12.[15] Plaintiffs further cite the R&R (ECF No. 2271 at 92-105),[16] but the R&R analyzed cases applying consumer protection statutes to ***prescription drugs***, not medical devices. Even as to drugs, none of those cases analyzed whether a prescription drug is a consumer good.[17]

Despite this Court's admonition that federal courts "interpret, not expand, state law[,]" MTD at 11 & n.18, Plaintiffs argue that an *Erie* analysis regarding "whether the Recalled Devices fit within the definition of a governing state statute" is unnecessary. Opp. at 12. Instead, they posit that "the broad scope" of five of the 16 statutes at issue is sufficient to let claims that would not be cognizable by reference to the definitions in the cited statutes stand. *Id.* (citing R&R at 92–105).[18] But where the states' highest courts have not addressed whether a drug or device is a consumer good under these statutes, and other courts have held that medical devices are ***not*** consumer goods as defined by the consumer protection statutes or analogous consumer protection laws, *Erie* compels a different analysis and result. *See, e.g.*, *Otis-Wisher*, 616 F. App'x at 435.

Simply put, for this Court to ignore that these statutes' scope is limited to claims concerning

---

[15] Plaintiffs argue the "key distinction" is that "Recalled Devices are sold to the user as the consumer whereas the surgical items are sold to the surgeon or dentist," Opp. at 12 (citing *In re Bextra & Celebrex Mktg. Sales Pracs.*, 495 F. Supp. 2d 1027, 1037 (N.D. Cal. 2007)), but the drugs in *Bextra* were not even "***sold to the user as the consumer***." *Id.* (emphasis added).

[16] In considering the West Virginia consumer protection statute, the R&R acknowledged *White*, but cited *West Virginia ex rel. McGraw v. Bristol Myers Squibb Co.*, No. 13-1603, 2014 WL 93569, at *6 (D.N.J. Feb. 26, 2014), to inappropriately cabin that decision. R&R at 103-04. *McGraw* simply stated that "*White's* decision is limited to private causes of action." *Id.* This matter, of course, is a private cause of action, so *McGraw* did not limit the relevant application of *White*, nor could it have because it was not decided by the West Virginia Supreme Court.

[17] *See In re Vioxx Class Cases*, 103 Cal. Rptr. 3d 83 (Cal. Ct. App. 2009) (R&R at 95); *Plubell v. Merck & Co., Inc.*, 289 S.W.3d 707 (Mo. Ct. App. 2009) & *Polk v. KV Pharm. Co.*, No. 09-CV-00588, 2011 WL 6257466 (E.D. Mo. Dec. 15, 2011) (R&R at 100). Other R&R "drug" cases address non-prescription drugs or were brought by private or public insurers, who make a choice, not available to a patient, regarding which drug to purchase or put on their formulary.

[18] Plaintiffs acknowledge the R&R did not analyze the scope of the Kentucky and Illinois statutes, but state, without support, "such an analysis should produce the same result." Opp. at 11 n.19.

the ***"personal, family, or household use"*** of goods, because goods or commerce is broadly defined, is to "interpret[] the language in such a way that one clause is rendered superfluous or meaningless for the benefit of another." *Orson, Inc. v. Miramax Film Corp.*, 79 F.3d 1358, 1374 (3d Cir. 1996). Further, in interpreting consumer protection statutes with the same language found in West Virginia's statute and others, this Court should consider how "other state supreme courts that have addressed the issue" as well as "federal courts interpreting that state's laws[.]" *Seaman v. Colvin*, 145 F. Supp. 3d 421, 426 (E.D. Pa. 2015). Thus, decisions like *White*, *Otis-Wisher*, *Collins*, and *Pease*[19] may not be set aside, and the consumer protection claims at issue here fail.

B. Omissions Cannot Support Wisconsin Deceptive Trade Practices Act Claims.

Plaintiffs contend that a Wisconsin DTPA claim is available when "partial statements . . . are rendered misleading by the omission of known facts." Opp. at 14. However, as explained in Section V, *supra*, Plaintiffs' Wisconsin DTPA claim still fails under this rule because a review of the PISAC's allegations reveals that purported "partial disclosures" are nothing of the sort—they are not affirmative statements but amount to puffery that neither concerned nor addressed the safety of the foam. *Tietsworth v. Harley-Davidson, Inc.*, 677 N.W.2d 233, 246 (Wis. 2004).

C. Seven Consumer Protection Claims Fail for Lack of Prerequisites to Suit.

Five consumer protection claims should be dismissed because Plaintiffs (i) failed to provide statutorily required timely and compliant pre-suit notice; (ii) did not attempt to resolve their Mississippi CPA claim through a statutorily mandated informal dispute settlement program; and (iii) waived their Alabama DTPA claim. MTD at 13-15, nn.27-30. Plaintiffs conclusorily

[19] Respironics also identified cases interpreting statutes related to the consumer protection statutes at issue that limit their scope to products "used for personal, family, or household purposes." MTD at 10–13. These cases all hold that pharmaceutical products are not within the scope of those statutes. Plaintiffs contend these cases are inapposite because the Consumer Product Safety Act "carves out 'drugs, devices, or cosmetics.'" Opp. at 13. But the logic is the same. These cases address FDA-regulated medical devices not available to consumers except by prescription.

allege providing ***post-suit*** notice of ***economic loss claims*** and offering—again post-suit—to participate in a dispute settlement program, satisfies ***pre-suit*** statutory requirements to allege personal injury claims. Opp. at 14. Not so. Nor is it a "fact question" whether ***facially deficient post-suit letters (incorporated by reference in the PISAC) concerning economic loss claims provide sufficient pre-suit notice of personal injury claims***. *Id.*

D. Certain Plaintiffs Lack Statutory Standing to Sue.

Plaintiffs in twelve states lack statutory standing to bring consumer protection claims. Contrary to Plaintiffs' assertions, Respironics did not waive its standing argument because such argument arises explicitly from the "supplemental portions of the amended master complaint" that "plead[ed]" for the first time "each relevant [consumer protection] statute in a separate count."[20] Opp. at 6.[21] Plaintiffs' argument that consumers who rented or used Recalled Devices are only "hypothetical plaintiffs" contradicts the PISAC, which, in "summar[izing] . . . the claims brought by all . . . [P]laintiffs,"[22] alleges that "Plaintiffs ***are*** consumers" who "leased[] or used Recalled Devices." *E.g.*, PISAC ¶¶ 651, 757 (emphasis added).

CONCLUSION

For all the foregoing reasons and those stated in Respironics' moving brief, the aforementioned claims in the PISAC should be dismissed in their entirety with prejudice.

---

[20] *See also Hazzouri v. W. Pittston Borough*, 416 F. Supp. 3d 405, 413 (M.D. Pa. 2019).

[21] Respironics' statutory standing argument has not been waived—nor could it be—because it relies on statutory language rather than caselaw. Opp. at 15. *NetQuote, Inc. v. Byrd*, 504 F. Supp. 2d 1126 (D. Colo. 2007), relied upon by Plaintiffs, Opp. at 15 n.15, does not suggest otherwise; it analyzed business, not individual, standing under Colorado's CPA. *See id.* at 1135.

[22] *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, 537 F. Supp. 3d 679, 720 (D.N.J. 2021) (describing function of a Master Complaint).

Dated: April 24, 2024

Respectfully Submitted,

/s/ John P. Lavelle, Jr.

John P. Lavelle, Jr. (PA54279)
john.lavelle@morganlewis.com
Lisa C. Dykstra (PA67271)
lisa.dykstra@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
2222 Market Street
Philadelphia, PA 19103-3007
Tel: 215.963.5000

Wendy West Feinstein (PA86698)
wendy.feinstein@morganlewis.com
MORGAN, LEWIS & BOCKIUS LLP
One Oxford Center, 32nd Floor
Pittsburgh, PA 15219-6401
Tel: 412.560.3300

Counsel for Defendant Philips RS North America LLC

CERTIFICATE OF SERVICE

I hereby certify that on April 24, 2024, the foregoing document was electronically filed with the Clerk of the Court and served upon counsel of record through the Court's ECF system.

/s/ John P. Lavelle, Jr.
John P. Lavelle, Jr.